

### REMARKS/ARGUMENTS

This paper is in response to the election/restriction requirement. Claims 86-123 are pending. Reconsideration and continued examination of this application is respectfully requested.

In the election/restriction requirement, the Examiner required Applicants to elect one of the following two alleged “species”:

“Species 1”: where the muscle tone sensor is mechanically coupled to:

- (A) the housing of an implantable device as shown in Figure 9A-B; or
- (B) the header of an implantable device as shown in Figure 9C; or
- (C) the lead of an implantable device as shown in Figure 9D.

“Species 2”: wherein a third sensor to detect a cardiac signal is configured to provide:

- (A) bradycardia pacing therapy; or
- (B) preventative arrhythmia therapy.

### ELECTION

In response, Applicants elect with traverse the alleged species 1. The election is with traverse for two reasons.

First, the wording used in the description of species 2 is unclear and confusing. The description appears to be based on the language of pending claims 118 and 120, which recite:

- 118: “... wherein the detector system further includes a third sensor configured to detect a cardiac signal, and wherein the therapy system is configured to provide bradycardia pacing therapy responsive to the detected cardiac signal and to the sleep state classification” (emphasis added); and
- 120: “... wherein the detector system further includes a third sensor configured to detect a cardiac signal, and wherein the therapy system is configured to provide preventative arrhythmia therapy responsive to the detected cardiac signal and to the sleep state classification” (emphasis added).

In these claims, the third sensor is “configured to detect” a cardiac signal, and the therapy system is “configured to provide” the recited therapy. The description of the “species 2”, however, omits mention of any therapy system, and states instead that the third sensor both

“detect[s] a cardiac signal” and “is configured to provide [the bradycardia pacing or preventative arrhythmia] therapy”. Unlike this description, none of the pending claims recite a sensor that is “configured to provide” therapy. Pending further clarification, the undersigned will presume the Examiner intended to describe for the “species 2” something such as: a system or method in which a third sensor is configured to detect a cardiac signal, and a therapy system is configured to provide bradycardia pacing therapy or preventative arrhythmia therapy.

Second, the election is with traverse because the alleged species ***are not species*** at all. Species are distinctly different embodiments that could fall within the scope of a generic claim and that are mutually exclusive. See MPEP §§ 806.04, 806.04(e), 806.04(f). For example, a nail and a screw can be considered to be mutually exclusive embodiments of a generic “fastener”.

In the present case, the specification clearly teaches embodiments that include both the “species 1” and the (properly understood) “species 2”. For example, the block diagram of FIG. 7 depicts a medical system 700 that includes a muscle atonia sensor 748 as well as a cardiac pulse generator 701, therapy control unit 742, and cardiac therapy electrodes 722:

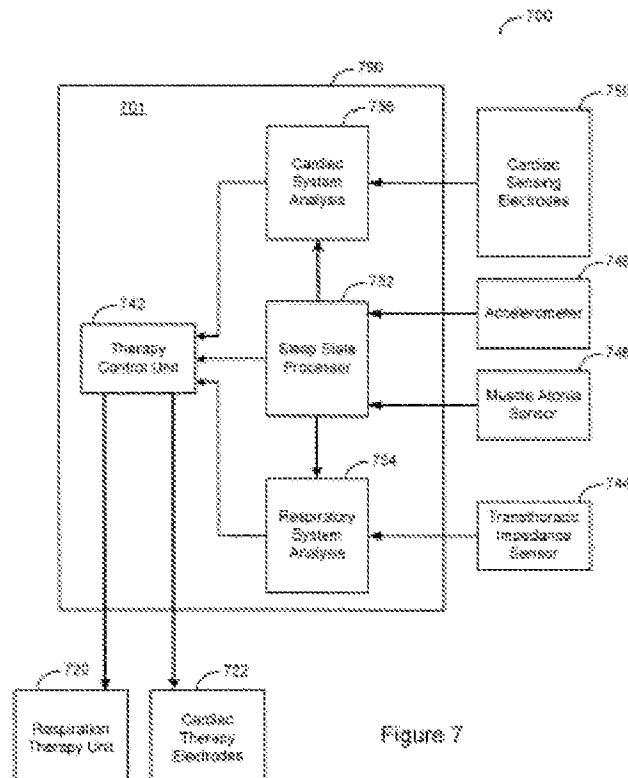


Figure 7

The description states that the pulse generator 701 is configured to provide therapy for cardiac arrhythmia, and that various cardiac therapies including bradycardia pacing and anti-tachycardia pacing, for example, may be implemented. See page 19, lines 16-20. The muscle atonia sensor 748 is described in further detail in FIG. 8, where FIGS. 7 and 8 can be considered to describe, among other things, individual embodiments that possess the features of both figures. (See page 19, lines 10-11, “Figures 7 and 8 illustrate a medical system that may be used to perform sleep state informed therapy in accordance with embodiments of the invention” (emphasis added).)

FIG. 8 is reproduced for convenience here:

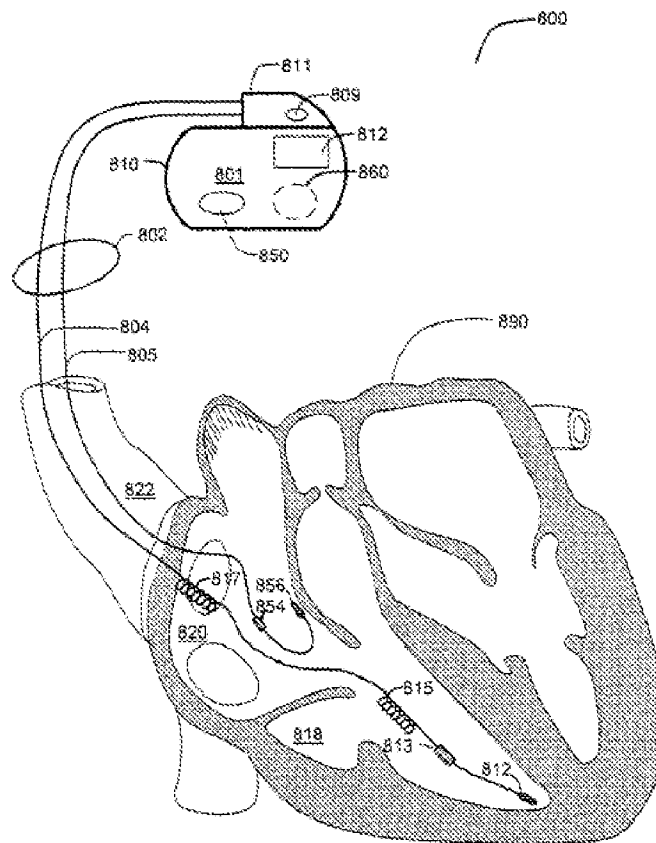


Figure 8

It depicts a cardiac rhythm management (CRM) system 800 that includes a medical device 801 and other components. The specification teaches that the medical device 801 can

function as a bradycardia pacemaker or anti-tachycardia pacemaker, for example. See page 22, lines 19-28. Also depicted are ventricular and atrial lead systems 804, 805, which include various electrodes to detect cardiac signals. See page 24, lines 1-14. The depicted embodiment also includes a muscle atonia sensor that is mechanically coupled to (“positioned ... in or on”) the housing 810, header 811, or lead system 802. See page 23, lines 18-22.

Thus, the specification describes a single embodiment that includes both (1) a muscle tone sensor mechanically coupled to the housing, header, or lead of an implantable device, and (2) a third sensor configured to detect a cardiac signal, and a therapy system configured to provide bradycardia pacing therapy or preventative arrhythmia therapy. This disclosure specifically refutes the assertion that “species” 1 and 2 are mutually exclusive.

Without mutual exclusivity, the “species” 1 and 2 cannot define proper species pursuant to MPEP § 806.04, and cannot justify an election requirement. The election of species requirement cannot be sustained and should be withdrawn.

#### **IDENTIFICATION OF CLAIMS**

In view of the non-exclusivity of the cited features, the claims that correspond to the second election are all of the pending claims 86-123. For example, claims 118 and 120 are included in the election even though they recite a third sensor configured to detect a cardiac signal and a therapy system configured to provide bradycardia pacing therapy or preventative arrhythmia therapy, respectively (“species 2”), because the specification teaches that systems that have such features can also have a muscle tone sensor mechanically coupled to the housing, header, or lead of an implantable device (“species 1”), and thus claims 118 and 120 also encompass the elected “species 1”.

## **CONCLUSION**

Applicants respectfully request reconsideration and withdrawal of the requirement for election as explained more fully above. If the Examiner would find it helpful to discuss this issue by telephone, the undersigned attorney invites the Examiner to contact him.

Respectfully submitted,

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